Participant Information Sheet

The INFORM Study: Identifying older peoples' needs to empower discussions with healthcare professionals about their use of anticholinergic medicines

The study chief investigator: Dr. Carrie Stewart

We would like to invite you to participate in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear, or you would like more information. If you agree to take part you will be asked to sign a consent form, a copy of which you will be able to keep.

What is the purpose of the study? Anticholinergics, a group of medicines, are used for common conditions including irritable bladder, allergies and sickness. Around half of all older adults use one or more of these medicines. The more anticholinergic medicines taken by a person, the greater their risk of side effects (e.g. constipation), and negative events such as developing dementia, falls and death. How best to reduce use of these medicines remains unknown. One approach proposed to reduce medication harms involves empowering patients.

Empowerment allows patients to have greater control by having a say in the decisions taken in relation to their health. While evidence suggests a role for empowering patients in relation to reducing the use of anticholinergic medicines, we do not know how best to achieve this.

Supporting our patient empowerment approach, our patient and public involvement (PPI) group (lay older persons and/or caregivers) co-developed an animated video (https://www.youtube.com/watch?v=3QcHKqQpr9E) and flyer to inform patients about the potential harms from anticholinergic medications. The study CI (CS) has recently interviewed health professionals (GPs, pharmacists, geriatricians) and found high acceptability of such an approach and these materials.

In this study we want to interview older people and caregivers of older people to explore what empowerment means to them. We want to know if they want to be empowered, and if so, identify what they need to be empowered in relation to decisions about anticholinergic medicines. We will look to find out what knowledge, skills and confidence is required and how to provide this to older people and caregivers.

What we learn from interviewing older people and caregivers will help us build a future intervention which can empower older people and caregivers to ask more questions about their anticholinergic medicines to allow them to be more informed about their medicines. In a future study we will hold workshops with stakeholders (older persons, caregivers and healthcare professionals) to co-develop this intervention. If you participate in this interview study, you will be invited to also participate in one of these workshops (but you do not have to participate in this follow-up study if you do not wish).

It is important to remember that while in many cases these medicines can be stopped, or switched for an alternative and safer medicine, it may be that for you the risks of using these medicines are lower than the risks of not treating the condition that the medicine has been prescribed for. Do not stop taking any of your medicines without discussing this with your health professional.

Why have I been chosen to take part? You have been invited to participate in this study as we have identified you as someone who is aged 65 years or older and who may use one or more of these anticholinergic medicines, or has used one of these medicines in the last 12 months. A list of these medicines is provided at the end of this information sheet. A member of our research team will check the medicines that you use before your interview.

You may wish to share the study information with the person who supports you with your medicines. This may be a partner, family member of friend. They are also invited to participate as a caregiver for a person using one or more of these medicines. Their participation is welcomed but not essential. If your caregiver/ care partner decides to participate, you will each have to provide signed consent and you will be interviewed separately. If required or convenient interviews could be conducted back to back.

Do I have to take part? No, it is up to you to decide whether or not to take part. If you decided not to take part, you do not need to do anything. If you do decide to take part, we will ask you to sign a consent form. Please keep this information leaflet in case you have any queries in the future.

What will happen if I decide to withdraw? If you decide to take part you are free to withdraw at any time, without reason. Data collected up until that point may still be used in the analysis.

What will happen to me if I take part? If you agree to take part a researcher will contact you by phone to check eligibility. The researcher will ask you to name the medicines that you take to ensure one or more of these medicines is an anticholinergic. If you are eligible to participate the researcher will then post or email a consent form to you. Upon receiving your signed consent, the researcher will arrange the interview date and time with you. The interviews are expected to last between 60 and 90 minutes. They will be audio-recorded and transcribed by an external company contracted by the University of Aberdeen for accuracy. The interviews can be completed at your home, by phone or online as preferred.

What are the possible disadvantages or risks of taking part? There are no identified disadvantages or risks to taking part in this study. However, we know that becoming aware of the potential risks of using these medicines may cause you some alarm. Do not stop taking any of your medicines without discussing this with your health professional. While in many cases these medicines can be stopped or switched for an alternative and safer medicine, it may be that for you the risks of using these medicines are lower than the risks of not treating the condition that the medicine has been prescribed for.

What are the possible benefits of taking part? There will be no personal benefit to you from participating in this study but your views will be valuable in shaping policy and improving the health and wellbeing of older people.

What if something goes wrong? If you have a concern about any aspect of this study, you should ask to speak to the study chief investigator (Dr. Carrie Stewart, contact details below) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the Research Governance Team by email: researchgovernance@abdn.ac.uk.

Will my taking part in this study be kept confidential? All information which is collected about you during the course of the research will be kept confidential within the study team and will have all identifying information removed. Participants will be reminded of the requirement for them to not disclose who attended their group and anything said by group members, however this cannot be guaranteed. Information will only be accessible to the research team but may be inspected by University of Aberdeen Research Governance staff or regulatory bodies such as Health Research Authority as

part of quality assurance and audit purposes to ensure the study has been carried out correctly.

What will happen to the data that you collect from me? The University of Aberdeen is the sponsor for this study based in the United Kingdom. We will be using information from *you* to undertake this study and the University of Aberdeen will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. If you withdraw from the study, we will keep the information about you that we have already obtained. Your rights to access, change or move this information are limited, as we need to manage the information in specific ways for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally identifiable information possible. You can find out more about how we use your information at: **http://www.abdn.ac.uk/privacy**

The University of Aberdeen will collect information from you for this research study in accordance with our instructions. We will use your name and the contact details you provide to contact you about the research study, and make sure that relevant information about the study is recorded and to oversee the quality of the study. The only people in the University of Aberdeen who will have access to information that identifies you will be people who need to contact you to arrange study visits or audit the data collection process. The University of Aberdeen will keep identifiable information about you from this study for 6 years after the study has finished. The University of Aberdeen will keep non-identifiable data about you on its computers and identifiable information about you as hard copy, for 6 years after the study has finished, in accordance with sponsor requirements and data legislation.

What will happen to the results of the research study? The results of this study will be reported in an academic journal article and/ or presented at an academic conference if a

suitable opportunity arises. What we learn from this study may also be used in student teachings if appropriate. You will not be identified personally in any of the reports or results from the study. A copy of the results will also be offered to all participants.

Who is organising and funding the research?

This study is being funded by the Sir Halley Stewart Trust (1106501521). This study is sponsored by the University of Aberdeen.

Who has reviewed this study?

Ethical approval has been obtained from the University of Aberdeen School of Medicine, Medical Sciences and Nutrition Ethics Review Board (SERB) Application ID 3238457.

What happens now?

Thank you for reading this information leaflet. Please take time to consider whether or not you think you would like to take part in this study. If you would like further information or ask questions, please do so. If you wish to take part, then we will ask you to sign a consent form.

Contact for further information.

Chief Investigator

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List of eligible medicines

Generic name	Brand name	Generic name	Brand name
Amantadine	Symmetrel™	**Loxapine**	Loxitane™
Amitriptyline	Elavil™	**Meclizine**	Antivert™
Amoxapine	Asendin™	**Meperidine**	Demerol™
Atropine	Sal-Tropine™	**Methocarbamol**	Robaxin™
Belladonna	Multiple	**Methotrimeprazine**	Levoprome™
Benztropine	Cogentin™	**Molindone**	Moban™
Brompheniramine	Dimetapp™	**Nefopam**	Nefogesic™
Carbamazepine	Tegretol™	**Nortriptyline**	Pamelor™
Carbinoxamine	Histex™, Carbihist™	**Olanzapine**	Zyprexa™
Chlorpheniramine	Chlor-Trimeton™	**Orphenadrine**	Norflex™
Chlorpromazine	Thorazine™	**Oxcarbazepine**	Trileptal™
Clemastine	Tavist™	**Oxybutynin**	Ditropan™
Clomipramine	Anafranil™	**Paroxetine**	Paxil™
Clozapine	Clozaril™	**Perphenazine**	Trilafon™
Cyclobenzaprine	Flexeril™	**Pimozide**	Orap™
Cyproheptadine	Periactin™	**Promethazine**	Phenergan™
Darifenacin	Enablex™	**Propantheline**	Pro-Banthine™
Desipramine	Norpramin™	**Propiverine**	Detrunorm™
Dicyclomine	Bentyl™	**Quetiapine**	Seroquel™
Dimenhydrinate	Dramamine™, others	**Scopolamine**	Transderm Scop™
Diphenhydramine	Benadryl™, others	**Solifenacin**	Vesicare™
Doxepin	Sinequan™	**Thioridazine**	Mellaril™
Doxylamine	Unisom™, others	**Tolterodine**	Detrol™
Fesoterodine	Toviaz™	**Trifluoperazine**	Stelazine™
Flavoxate	Urispas™	**Trihexyphenidyl**	Artane™
Hydroxyzine	Atarax™, Vistaril™	**Trimipramine**	Surmontil™
Hyoscyamine	Anaspaz™, Levsin™	**Trospium**	Sanc
Imipramine	Tofranil™		